K 000019

MAR 2 9 2000

Medist International
9160 Highway 64, Suite 12
Lakeland, TN 38002
Phone: (901) 380-9411
Fax: (901) 389-8412

510(K) SUMMARY

(As required by section 21 CFR 807.92(c))

Submitter's name:	Medist International
Submitter's address:	9160 Highway 64, Suite 12, Lakeland, TN 38002
Submitter's telephone number:	(901) 380-9411
Contact Person:	Bernard F. Grisoni
Submission date:	January 3, 2000
Trade Name:	*Single size Tendon Spacer (name subject to change)*
Common Name:	Tendon Spacer
Classification Name:	Prosthesis, Tendon, Passive
Legally marketed predicate devices:	Wright Medical Technology Swanson Tendon Spacer

Device description:
The Single Size Tendon Spacer is designed to facilitate the two-step tendon reconstruction surgery. The device is 50 cm long, and its oval cross section increases progressively over its length from 3.0 x 1.5 mm to 3.0 mm x 6.0 mm. The spacer slope is designed to match shapes and dimensions of the digital canal. The spacers are made of high performance medical grade silicone elastomer containing barium sulfate to provide radio-opacity. During the first stage of the reconstruction surgery, the spacer is placed into the reconstructed tendon bed and slid until optimum fit is achieved. The tendon is attached to the distal phalanx and the proximal spacer end is left free in the palm or forelimb. Excess spacer material is cut off. The second stage of surgery is performed 2 to 6 months later, once an appropriate pseudo-sheath has been created around the spacer, and tissues are soft and pliable. The spacer is then removed and replaced by a permanent active tendon autograft. The device is not intended as permanent implant or to function as a replacement for a ligament or tendon.

Indication for use:
Scarred or adhering tendons due to trauma or failed primary repair.
Absence of tendon sheath.
Scarred or adherent non-functional tendon pulleys.
Ruptured tendon.

Technological characteristics:
The Single Size Tendon Spacer device has the equivalent technological characteristics (i.e. chemical composition, and mechanical strength) to the predicate device.

Performance data:
Studies demonstrated that the Single Size Tendon Spacer devices have the equivalent mechanical strength and biocompatibility performances to the predicate device.

Basis for substantial equivalence:
The Single Size Tendon Spacer device is safe and effective because they are equivalent to the predicate devices in terms of chemical composition, indication of use, and product performances.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2000

Bernard F. Grisoni, Ph.D.
Medist International
9160 Highway 64
Suite 12
Lakeland, Tennessee 38002

Re: K000019
CD Spinal System
Single Size Tendon Spacer
Product Code: HXT
Dated: January 3, 2000
Received: January 4, 2000

Dear Dr. Grisoni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lachman

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K000019

Device Name: Single Size Tendon Spacer

Indication For Use:

Surgical indications for the Single Size Tendon Spacers include: Scarred or adhering tendons due to trauma or failed primary repair. Absence of tendon sheath. Scarred or adherent non-functional tendon pulleys. Ruptured tendon. The device is single use, temporary implantation for 2 to 6 months.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000019

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)